

REMARKS/ARGUMENTS

This Amendment has been prepared in response to the non-final Office Action taken with respect to the above-identified patent application on October 31, 2005. With respect to this Action, applicants, noting that their last Amendment overcame the claim rejection then made in this case, have carefully studied the Examiner's comments, along with the now newly cited and applied references, and propose herein new claim 2 (which replaces cancelled claim 1) with respect to which they urge the Examiner to recognize that their so-claimed invention is plainly distinguishable from, and therefore patentable over, the newly cited and applied prior art. That newly cited and applied art, which the Examiner has applied to applicant's now-cancelled claim 1 under 35 U.S.C. § 103(a), includes U.S. Patent No. 5,003,983 to Dingwall *et al.*, U.S. Patent No. 5,891,047 to Lander *et al.*, and U.S. Patent No. 6,112,116 to Fischell *et al.* The Examiner urges that a combination of these three references makes obvious applicants' invention.

Applicants fully disagree with the Examiner's position, and point out below how their claimed invention distinguishes significantly over the proposed, combined references, and is thus non-obvious and patentable.

It is very important for the Examiner to recognize that what applicants are claiming is a method for detecting, with great confidence, and from a conventional ECG waveform, *a person's significantly confirmed condition of myocardial infarction*. The art cited and applied by the Examiner neither shows nor suggests any methodology whatsoever which leads from the acquiring of a person's ECG waveform, through plural-step EGC processing that goes beyond taking a look merely at ST-deviation level *per se*, to furnish a definitive and highly confirmable

“statement” regarding the presence or absence of *myocardial infarction*. Indeed, the cited and applied art, which, at best, carries ECG processing only to a point of determining whether there is evidence of an ST deviation which is greater than some predetermined deviation level, neither shows nor suggests, *among other things*, two, key, further, important ECG processing/analyzing steps [referred to in new Claim 2 as (a) “analyzing” ST deviation, and (b) “implementing” selected pathological thresholding, steps, respectively] which lie at the heart of applicants’ invention. Very specifically, there is no teaching or suggestion in the art regarding analyzing a detected ST deviation in an ECG waveform for *benignity* or *non-benignity*. Neither is there any teaching or suggestion regarding thereafter implementing selected pathological thresholding where a non-benign ST deviation is determined to exist. Presence of the sequence of these two steps is key to the successful practice of applicants’ invention.

The Dingwall *et al.* reference, the principal reference relied upon by the Examiner, and notwithstanding the Examiner’s assertion to the contrary, teaches really what applicants believe is but a single “thresholding” step in relation to analyzing a person’s ECG waveform. In this context, it should be noted that applicants’ rejected Claim 1 (now cancelled without prejudice) referred to *two* “thresholding” steps. Both of these steps remain as recited steps in applicants’ new Claim 2, but are now referred to, with different terminology, as (1) an “analyzing” step, and (2) an “implementing” step. The single Dingwall *et al.* reference step is one which is performed simply to identify, in a yes/no manner, whether content in a person’s ECG waveform *indicates a condition of myocardial ischemia*. According to Dingwall *et al.*, this yes/no myocardial ischemia determination is based upon the simple finding *per se* in an ECG waveform

of an ST deviation which exceeds a predetermined level of deviation.

Regarding the issue of “plural (two) thresholding steps”, which is relevant to the Examiner’s position of claim rejection in the above-referred-to recently taken Office Action, if the Examiner will please look very carefully again at the Dingwall *et al.* reference, not only will he discover that its teachings take one no further than describing effectively a one-step method for detecting only *myocardial ischemia*, but also that the believed “one-stepness” of this method becomes quite evident from a close and thoughtful reading of the Dingwall *et al.* specification text portions to which the Examiner points as being illustrative, so he asserts, of two, different “thresholding” steps. What the Examiner will find is that these specification text portions, in slightly different verbiage, describe the same, single activity involving looking for an ST deviation which exceeds some predetermined level.

According to Dingwall *et al.*, the presence or absence of *myocardial ischemia* can be discerned by the single step of comparing the width of certain pulses which are produced in conjunction with the vertical position of the ST segment of an ECG waveform in relation to a neutral axis. All determination of *myocardial ischemia* is done through the single step of looking at the width of such a pulse in comparison to the width of a normal pulse whose width indicates what has been determined, by the practice of the Dingwall *et al.* invention, to relate to a normally-positioned (*i.e.*, neither elevated nor depressed) ST waveform segment. Dingwall *et al.* goes not at all beyond this single step determination.

Regardless, however, of whether or not Dingwall *et al.* proposes a single- or plural-step approach to determining a certain level of ST deviation as an indicator of *myocardial*

ischemia, this reference says nothing whatsoever about detecting the presence or absence of *myocardial infarction*. Dingwall *et al.* stops at the point of determining merely ST-deviation presence, and ST-deviation level above some predetermined level.

Significantly, and as applicants have discovered and expressed in their now-presented claim to invention, ST-deviation-level data *per se*, such as the Dingwall *et al.*-gathered ST-deviation data (presence and amount), without the implementation thereto of significantly more processing and investigating activity, is simply not capable of confirmedly indicating the presence or absence of *myocardial infarction*.

In relation to the §103 applicability to applicants' claimed invention of the other cited and applied prior art Fischell *et al.* and Lander *et al.* patents, taken in combination with Dingwall *et al.*, the subject of this very important discovery by applicants regarding the non-utility and "erroneousness" of using ST-deviation level *per se* as an indicator of myocardial infarction helps to demonstrate why applicants' claimed invention is *not obvious*.

The cited and applied Fischell *et al.* reference provides an excellent illustration of the above-stated "erroneousness" regarding what turns out to be a prior art assumption that a confirmed condition of myocardial infarction can be determined simply by noting the presence or absence of an ST deviation which is above a certain level. This faulty assumption is what this reference implements in its described practice. Specifically, the Fischell *et al.* reference essentially says that ST deviation above a certain level can be used to declare myocardial infarction, and then indicates various ways in which such declaration information can be used in relation to a patient. Because the Fischell *et al.* reference is based upon this flawed assumption, its practice thus goes

no further than relying on the presence of an above-certain-level ST deviation. The reference fails to recognize that further information-processing regarding such ST-deviation data is necessary in order confirmedly to make a myocardial infarction "declaration".

The Lander *et al.* reference focuses principal attention (a) on the use of the QRS complex portion of an ECG waveform, and to some extent (b) on the use of the ST portion of such a waveform, to detect "abnormal activation" of the heart. Abnormal heart activation is said to include both myocardial ischemia and myocardial infarction. The reference mentions, effectively, the practice of noting the *presences* and *levels* of ST deviations in an ECG waveform as being indicative of *myocardial ischemia*. Myocardial infarction, is taught to be determined in a manner which is based on factors *other than ST deviation*. In other words, the reference does not use ST-deviation data to assess a condition of myocardial infarction.

Thus, with respect to using ST-deviation information which is present in an ECG waveform, none of the cited and applied prior art references goes beyond simply determining the presence or absence of an ST-deviation which is above a certain predetermined level. None of the references teaches, let alone recognizes, that ST-based information, beyond simply ST-deviation presence and level information, must be developed through additional processing of ST-deviation data before myocardial infarction can be confirmedly declared.

Applicant's invention, regarding the issue of confirmedly determining the presence or absence of myocardial infarction from ECG ST-deviation data goes well beyond simply determining if ST deviation is present, and whether that deviation is larger than some predetermined level. Applicants have recognized that such limited ST-deviation data is not

enough to declare the presence or absence of myocardial infarction. The combined steps of applicants' claimed invention, which importantly involve going significantly beyond the acquiring of simple ST-deviation presence and level data, are clearly not shown or suggested by the cited and applied prior art. Indeed, this prior art offers no clue whatsoever about processing ECG ST-deviation data beyond simply detecting ST-deviation presence and level, and most certainly does not show or suggest the combinational organization of plural method steps claimed herein by applicants to reach a confident conclusion regarding myocardial infarction.

In review, Dingwall *et al.* uses ST-deviation presence and level information to determine *myocardial ischemia* which, while related to *myocardial infarction*, is not the same thing. Fischell *et al.* utilizes ST-deviation presence and level information, *without more*, to declare the presence of myocardial infarction. It thus directly implements the flawed practice mentioned above which is "corrected" by the unique approach offered by applicants' invention. Lander *et al.* discusses using ST-deviation presence and level information, but only for the purpose of assessing a condition of myocardial ischemia

By the present Amendment, and apart from the fact that applicants fully believe that Claim 1, as presented prior to the entry of this Amendment, is fully patentable over the cited and applied references, applicants nonetheless propose herein new Claim 2, as a replacement for cancelled Claim 1, to give a fuller definition of the important and differentiating features which both lie at the heart of applicants' invention, and serve easily to distinguish applicants' claimed invention, in all respects, over the cited and applied prior art.

For the reasons given above, applicant's new Claim 2, as it is now presented with

entry of this Amendment, is believed to be clearly distinguishable in all ways over the applied prior art references. Accordingly, favorable reconsideration of this application, and early allowance now of the single claim in this case, are respectfully solicited. If the Examiner has any questions regarding the amendment or remarks, the Examiner is invited to contact Attorney-of-Record Jon M. Dickinson, Esq., at 503-504-2271.

Provisional Request for Extension of time in Which to Respond

Should this response be deemed to be untimely, Applicants hereby request an extension of time under 37 C.F.R. § 1.136. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any over-payment to Account No. 22-0258.

Customer Number

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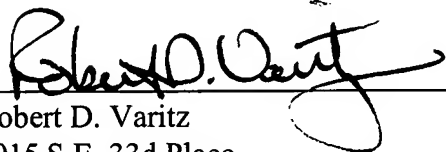
Respectfully Submitted,

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